

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 12, 2007

MEMORANDUM

SUBJECT: Review of "*Measurement of Transfer of Permethrin and Piperonyl Butoxide Residues from Vinyl and Carpet Flooring Treated with a Fogger Formulation as a Function of Time*"

FROM: Charles Smith, Environmental Scientist/Risk Assessor
Reregistration Branch 2
Health Effects Division (7509P)

LCSE 9/12/07

THRU: Jeff Evans, Biologist
Chemistry Exposure Branch
Health Effects Division (7509P)

A handwritten signature, likely of Jeff Evans, consisting of a stylized 'J' and 'E'.

TO: **Cathryn O'Connell**
Special Review and Reregistration Division (7508P)

DP Barcode: 336768

PC Code: 109701 and 067501

MRID Number: 461886-26

Attached is a review of the MRID 461886-26 "*Measurement of Transfer of Permethrin and Piperonyl Butoxide Residues from Vinyl and Carpet Flooring Treated with a Fogger Formulation as a Function of Time*" submitted by the Non-Dietary Exposure Task Force. The purpose of the study was to determine the amount of residue left on a hand and percale (roller) exposed to either carpet or vinyl flooring after application of a formulation containing permethrin (PER) and piperonyl butoxide (PBO) from 4 hours after application up to 336 hours after application.

Four Simulated Residential Rooms were used in this study. One room contained the sprayboom apparatus and treated vinyl and carpet flooring. Two other rooms were used to store the treated carpet and vinyl flooring sections for the roller press and one room was used for the hand press procedure. Vinyl flooring or carpet sections were pinned onto a sheet of plastic-covered plywood attached to the top of six 40 in x 40 in wooden platforms. Application of the test

material to the flooring was made using a sprayboom apparatus that simulated a ready-to-use fogger application. The desired deposition rate of the test material was 3.96 ug/cm^2 for PER and for PBO. Total deposition was measured using deposition coupons, which were collected after application of the test material followed by a drying period. After collection of the deposition coupons, carpet and vinyl flooring sections were removed and moved to their separate rooms. For the hand press procedure, test subjects performed one hand press with each hand on separate treated surfaces at each sampling interval. The subjects' hands were cleaned with isopropyl alcohol dressing sponges to remove any remaining residues after each hand press. For the indoor roller procedure, an indoor roller assembly was fitted to the platforms to collect the roller samples. The roller samples were also conducted using separate treated surfaces for each sampling interval. The dressing sponges, deposition coupons, and percale roller samples were extracted and then analyzed for PER using a GC system and for PBO using a HPLC system.

The study reported that deposition ranged from 4.68 to 5.75 ug/cm^2 for PER and from 3.94 to 4.81 ug/cm^2 for PBO. The PBO deposition coupon residue data was corrected for an average field fortification recovery of 85.4%. The corrected deposition values for PBO ranged from 4.58 to 5.62 ug/cm^2 . The average deposition value for each type of run was used in the percent transferability (percent of application) calculations.

Average PER and PBO residues transferred from vinyl to the hand were highest after 4 hours and lowest after 336 hours. The calculated average values ranged from 2.01 to 271.42 ng/cm^2 for PER and from 1.19 to 160.26 ng/cm^2 for PBO. The average residues transferred from carpet to the hand were highest after 4 hours for PER and PBO (192.96 and 168.76 ng/cm^2 , respectively) and lowest after 168 hours for PER (128.68 ng/cm^2) and after 336 hours for PBO (90.57 ng/cm^2).

Average residues transferred from vinyl to the percale were highest after 4 hours for PER and PBO (114 and 63 ng/cm^2) and lowest after 336 hours for PER (1 ng/cm^2) and 168 hours for PBO (1 ng/cm^2). For the transfer from carpet to the percale, average residues were highest after 24 hours for PER (267 ng/cm^2) and PBO (205 ng/cm^2) and lowest after 12 hours for PER (206 ng/cm^2) and 336 hours for PBO (132 ng/cm^2).

Residues remaining on hands and percale following contact with either a treated vinyl or carpet flooring surface were determined from 4 hours after application to 336 hours after application. The percent of residue transferred from vinyl to the hands was calculated to range from 5.14% for PER and 3.05% for PBO at 4 hours after application to 0.04% for PER and 0.02% for PBO at 336 hours after application. The percent of residue transferred from carpet to the hands was calculated to range from 3.79% for PER and 3.59% for PBO at 4 hours after application to 2.53% for PER and 1.93% for PBO at 168 and 336 hours after application, respectively. The percent of residue transferred from vinyl to the percale was calculated to range from 2.08% for PER and 1.17% for PBO at 4 hours after application to 0.02% for PER at 336 hours after application and 0.02% for PBO at 168 hours after application. The percent of residue transferred from carpet to the percale was calculated to range from 5.7% for PER and 4.4% for PBO at 24 hours after application to 4.4% for PER and 2.8% for PBO at 12 and 336 hours after application, respectively.

In general, the PER and PBO residues transferred from treated vinyl to either percale or bare hands decreased rapidly over time and PER and PBO residues transferred from treated carpet to either percale or bare hands decreased slowly over time. For vinyl, the percent of PER and PBO transferred to bare hand was higher than that transferred to percale. For carpet, the percent of PER and PBO transferred to percale was higher than that transferred to bare hand.

The primary review for this study was conducted by Versar, Inc. A secondary review was conducted by the Health Effects Division (HED). The protocol provided with the study along with OPPTS Series 875 Part B, Guideline 875.2300: Indoor Surface Residue Dissipation, Postapplication and Part C Guidelines were used to review the study. Overall, both the performance of this study and the data generated in this study conformed to the criteria set forth in the protocol and guidelines. HED believes the data within this study is of high quality and valid for risk assessment purposes.



MEMORANDUM

TO: Margarita Collantes cc: 110082.4000.001.01
FROM: Karie Riley/Linda Phillips
DATE: March 22, 2004
SUBJECT: Review of "*Measurement of Transfer of Permethrin and Piperonyl Butoxide Residues from Vinyl and Carpet Flooring Treated with a Fogger Formulation as a Function of Time*" (Project #: 00-045-PY01)

This report reviews a study entitled "*Measurement of Transfer of Permethrin and Piperonyl Butoxide Residues from Vinyl and Carpet Flooring Treated with a Fogger Formulation as a Function of Time.*" The protocol provided with the study along with OPPTS Series 875 Part B, Guideline 875.2300: Indoor Surface Residue Dissipation, Postapplication and Part C Guidelines were used to review the study.

Reviewers: Karie Riley/Linda Phillips

Date: March 22, 2004

STUDY TYPE: Active Transfer; Vinyl & Carpet, Transferability over time (roller and hand press)

TEST MATERIAL: Permethrin and Piperonyl Butoxide; pre-fill batch formulation (similar to that of an indoor fogger formulation)

SYNONYMS: Permethrin (PER) and Piperonyl Butoxide (PBO)

CITATION:

Study Director/Author(s):	Sami Selim, Ph.D.
Title:	<i>Measurement of Transfer of Permethrin and Piperonyl Butoxide Residues from Vinyl and Carpet Flooring Treated with a Fogger Formulation as a Function of Time</i>
Study Completion Date:	October 1, 2003
Testing Facility:	Toxcon Health Sciences Research Centre Inc. 9607 - 41 st Avenue Edmonton, Alberta Canada T6E 5XL
Analytical Facility:	EN-CAS Laboratories 2359 Farrington Point Drive Winston-Salem, NC 27107
Identifying Codes:	Toxcon Project ID: 01-028-PY01 EN-CAS Project No.: 01-0041

SPONSOR: Non-Dietary Exposure Task Force

EXECUTIVE SUMMARY:

This report reviews “*Measurement of Transfer of Permethrin and Piperonyl Butoxide Residues from Vinyl and Carpet Flooring Treated with a Fogger Formulation as a Function of Time*” submitted by the Non-Dietary Exposure Task Force. The purpose of the study was to determine the amount of residue left on a hand and percale (roller) exposed to either carpet or vinyl flooring after application of a formulation containing permethrin (PER) and piperonyl butoxide (PBO) from 4 hours after application up to 336 hours after application.

Four Simulated Residential Rooms (SRRs) were used. One room contained the sprayboom apparatus and treated vinyl and carpet flooring. Two other rooms were used to store the treated carpet and vinyl flooring sections for the roller press and one room was used for the hand press procedure. Vinyl flooring or carpet sections were pinned onto a sheet of plastic-covered plywood attached to the top of six 40 in x 40 in wooden platforms. Application of the test material to the flooring was made using a sprayboom apparatus. The desired deposition rate of the test material onto the vinyl flooring was 3.96 $\mu\text{g}/\text{cm}^2$ for PER and for PBO. Total deposition was measured using deposition coupons, which were collected after application of the test material followed by a drying period. After collection of the deposition coupons, carpet and vinyl flooring sections were removed and moved to their separate rooms. For the hand press procedure, test subjects performed one hand press with each hand on separate treated surfaces at each sampling interval. For the indoor roller procedure, an indoor roller assembly was fitted to the platforms to collect the roller samples. The roller samples were also conducted using separate treated surfaces at each sampling interval. The subjects’ hands were cleaned with isopropyl alcohol dressing sponges to remove any remaining residues after each hand press. The dressing sponges, deposition coupons, and percale roller samples were extracted and then analyzed for PER using a GC system and for PBO using a HPLC system.

The study author reported that deposition ranged from 4.68 to 5.75 ug/cm^2 for PER and from 3.94 to 4.81 ug/cm^2 for PBO. Versar corrected the PBO deposition coupon residue data for an average field fortification recovery of 85.4%.

Corrected deposition values for PBO ranged from 4.58 to 5.62 ug/cm². The average deposition value for each type of run was used in the percent transferability (percent of application) calculations.

According to both the study author's and Versar's calculations, average PER and PBO residues transferred from vinyl to the hand were highest after 4 hours and lowest after 336 hours. The study author calculated average values ranging from 0.91 to 271.42 ng/cm² for PER and from 0.0 to 160.26 ng/cm² for PBO. Versar calculated average values ranging from 2.01 to 271.42 ng/cm² for PER and from 1.19 to 160.26 ng/cm² for PBO. As all PER and PBO residues transferred to bare hands from carpet were above the LOQ, the study author's and Versar's calculations for this portion of the study were in agreement. The average residues transferred from carpet to the hand were highest after 4 hours for PER and PBO (192.96 and 168.76 ng/cm², respectively) and lowest after 168 hours for PER (128.68 ng/cm²) and after 336 hours for PBO (90.57 ng/cm²).

According to both the study author's and Versar's calculations, the average residues transferred from vinyl to the percale were highest after 4 hours for PER and PBO (114 and 63 ng/cm²) and lowest after 336 hours for PER (1 ng/cm²) and 168 hours for PBO (1 ng/cm²). For the transfer from carpet to the percale, average residues were highest after 24 hours for PER (267 ng/cm²) and PBO (205 ng/cm²) and lowest after 12 hours for PER (206 ng/cm²) and 336 hours for PBO (132 ng/cm²).

Residues remaining on hands and percale following contact with either a treated vinyl or carpet flooring surface were determined from 4 hours after application to 336 hours after application. The percent of residue transferred from vinyl to the hands after application was reported by the study author to range from 5.14% for PER and 3.57% for PBO at 4 hours after application to 0.02% for PER and 0.0% for PBO at 336 hours after application. The percent of residue transferred from carpet to the hands after application was reported by the study author to range from 3.79% for PER and 4.20% for PBO at 4 hours after application to 2.53% for PER and 2.25% for PBO at 168 and 336 hours after application, respectively. The percent of residue transferred from vinyl to the percale after application was reported by the study author to range from 2.08% for PER and 1.38% for PBO at 4 hours after application to 0.02% for PER at 336 hours after application and 0.02% for PBO at 168 hours after application. The percent of residue transferred from carpet to the hands after application was reported by the study author to range from 5.69% for PER and 5.15% for PBO at 24 hours after application to 4.39% for PER at 12 hours after application and 4.12% for PBO at 168 hours after application.

Versar also calculated the percent of residue transferred from vinyl flooring and carpet to bare hands and percale. The percent of residue transferred from vinyl to the hands was calculated by Versar and ranged from 5.14% for PER and 3.05% for PBO at 4 hours after application to 0.04% for PER and 0.02% for PBO at 336 hours after application. The percent of residue transferred from carpet to the hands was calculated by Versar and ranged from 3.79% for PER and 3.59% for PBO at 4 hours after application to 2.53% for PER and 1.93% for PBO at 168 and 336 hours after application, respectively. The percent of residue transferred from vinyl to the percale was calculated by Versar and ranged from 2.08% for PER and 1.17% for PBO at 4 hours after application to 0.02% for PER at 336 hours after application and 0.02% for PBO at 168 hours after application. The percent of residue transferred from carpet to the percale was calculated by Versar and ranged from 5.7% for PER and 4.4% for PBO at 24 hours after application to 4.4% for PER and 2.8% for PBO at 12 and 336 hours after application, respectively.

In general, the PER and PBO residues transferred from treated vinyl to either percale or bare hands decreased rapidly over time and PER and PBO residues transferred from treated carpet to either percale or bare hands decreased slowly over time. For vinyl, the percent of PER transferred to percale or bare hands is higher than the percent of PBO transferred. For carpet, the percent of PER transferred to percale or bare hands is similar to the percent of PBO transferred to percale or bare hands. Additionally, for vinyl, the percent of PER and PBO transferred to bare hand was higher than transferred to percale. For carpet, the percent of PER and PBO transferred to percale was higher than transferred to bare hand.

The protocol provided with the study along with OPPTS Series 875 Part B, Guideline 875.2300: Indoor Surface Residue Dissipation, Postapplication and Part C Guidelines were used to review the study. Overall, the majority of the procedures performed and the quality of the data generated in this study conformed to the criteria set forth in the protocol and guidelines. However, certain issues of concern were noted:

- A specific application rate was not provided in the Study Report. Application was based on a target deposition rate determined in another study.
- Calibration procedures for the application equipment were not provided in the Study Report. It is not certain if the equipment used in this study was consistent with the proposed use for this product. A label was not provided with the study. The label recommended application method is not known.
- The study author did not correct the PBO coupon deposition residue data for field fortification recoveries, which were below 90%.
- The method validation recoveries were not provided in the Study Report.

COMPLIANCE:

Signed and dated GLP, Data Confidentiality and Quality Assurance statements were provided. The Study Report noted that the study was performed according to the U.S. EPA FIFRA Good Laboratory Practice Regulations currently in effect (40 CFR, Part 160), with certain exceptions: (1) conventional and digital photography was not done according to GLP Regulations and the resulting photographs are considered non-GLP, (2) scanning of hand palmar surface area to create a digital image and the computerized method of calculating surface area was not done according to GLP Regulations, and (3) information recorded on subject entry, exit and hand inspection forms was not entered and/or corrected according to GLP Regulations.

GUIDELINE OR PROTOCOL FOLLOWED:

The study was conducted following EN-CAS and Toxcon Standard Operating Procedures and the protocol of the Non-Dietary Exposure Task Force (Toxcon Protocol No. 00-045-PY01).

I. MATERIALS AND METHODS

A. Materials:

1. Test Material:

Formulation: An unidentified pre-fill formulation similar to that for an indoor fogger; developed by McLaughlin Gormley King Company (MGK)

Lot/Batch # :

Lot Number	Batch Number	% PER	% PBO
PYO1T009	0110-1	0.770	0.749
	0110-2	0.769	0.749
	0110-3	0.760	0.743
	0110-4	0.753	0.735
	GLP-1474	0.795	0.745

Formulation guarantee: Certificate of analyses provided.
CAS #(s): PER: 52645-53-1
PBO: 51-03-6
Other Relevant Information: Toxcon ID No.: PY01T009

2. Relevance of Test Material to Proposed Formulation(s):

Permethrin and piperonyl butoxide are active ingredients used in formulated consumer products intended for use in residential buildings. The product used was a pre-fill batch formulation similar to that for an indoor fogger formulation developed by McLaughlin Gormley King Company (MGK). The name and label for the test product was not provided with the study.

B. Study Design:

There were two amendments and three deviations from the study protocol.

The amendments included: (1) In Section 15.2, the text changed from “1 to 2 times the target LOQ of the analytical method” to “approximately 10.0 mg for alpha cellulose, 1.80 mg for ½ roller size percale, and 100 ug for wipes”. In Section 15.2, the text changed from “equal to at least 5 times the LOQ and up to the maximum anticipated residue” to “approximately 50.0 mg for alpha-cellulose, 72.5 mg for ½ roller size percale, and 4,000 ug for wipes”. In table 1B, the coupon number “8” was changed to “18” in the 72 hr column; and (2) The Sponsor Representative and Submitter for the Non-Dietary Exposure Task Force was changed to David Carlson.

The deviations included: (1) Several subjects did not have the palmer surface paint imprint done prior to the study and subject #2 was processed and exposed without medical personnel in attendance; (2) For the hand pressing of carpet at the 168-hour time point, coupon #5 was used for Subject #2 right hand’s hand press instead of coupon #56. Therefore, Subject #1 was required to use coupon #56 instead of coupon #5 for the right hand’s hand press; and (3) Page 1 of 5 in the Test Sample Chain of Custody for the sample shipment sent to EN-CAS on November 12, 2001 was inadvertently not sent out with the rest of the shipment. It was faxed to EN-CAS on November 15, 2001. It does not appear that the deviations had a negative impact on the study.

1. Site Description:

Test locations: The test site was located at the Toxcon Health Sciences Research Centre in Canada. Four test rooms (Simulated Residential Rooms (SRRs)) were used with one containing the application equipment (the sprayboom). The rooms were prepared according to Toxcon SOP No. E-025: *Preparation of Test Rooms Prior to an Experiment*.

Meteorological Data: Target test room conditions prior to application included an air exchange rate of 0.6 ± 0.1 air change per hour (ACH), a temperature of $72 \pm 4^{\circ}\text{F}$, and a relative humidity of $50 \pm 10\%$.

Ventilation/Air-Filtration: The ventilation system for the application room was turned off (dampers closed) during application and for three hours after application. The dampers were opened after the three hours and the room conditions were adjusted to reach the conditions prior to application for a 30 minute drying period.

2. Surface(s) Monitored:

Room(s) Monitored: Four SRRs were used. One room contained the sprayboom apparatus and treated vinyl and carpet flooring. Two other rooms were used to store the treated carpet and vinyl flooring sections for the roller press and one room was used for the hand press procedure.

Room Size(s): 16 ft x 16 ft x 8 ft

Types of Surface(s): Vinyl and carpet flooring

Surface Characteristics: Vinyl and carpet flooring sections were pinned onto a sheet of plastic-covered plywood attached to the top of six 40 in x 40 in wooden platforms. Each platform for the hand press experiment included 4 deposition coupons and 11 flooring sections. Each platform for the roller experiment included 5 deposition coupons and 2 flooring sections. The carpet and vinyl flooring specifications were provided in the protocol. The vinyl flooring

was made by DOMCO Inc. and featured a no-wax vinyl finish. The carpet was manufactured by KRAUS and was made of saxony cut pile (100% BCF nylon) and pre-treated with Master Guard. The tufted pile was 1,220 g/m² and the machine gauge was 31.4 rows/10 cm.

Areas sprayed and sampled: The carpet and vinyl flooring sections in one of the three SRRs used in this study were sprayed and sampled for PER and PBO residues.

Other products used: N/A

3. Physical State of Formulation as Applied : Fogger

4. Application Rates and Regimes:

Application Equipment: Sprayboom

Application Regime: Six sprayboom runs (conducted on separate days) were conducted in one SRR. The runs included two for the vinyl roller procedure, two for the carpet roller procedure, one for the carpet hand press procedure and one for the vinyl hand press procedure.

Application rate(s): An application rate was not provided in the Study Report. Application was based on the desired deposition rate of the test material onto the vinyl flooring. For PER and PBO, the desired deposition rate was 3.96 µg/cm². Deposition rates were based on results of indoor PER and PBO total release fogger deposition studies. The sprayboom nozzle sweep speed required to obtain the desired deposition was calculated using the following equation: $U = [(Q_t)(F_a)(k_1)/(R)(n)(d)(10^{-6})]$, where U is the sprayboom nozzle sweep speed (cm/s), Q_t is the nozzle output rate (g/s), F_a is the fraction of pyrethrin in the formulation, R is the target deposition rate of PY (µg/cm²), d is a fixed value representing the distance between nozzles (71.2 cm), n is the number of nozzles (5), and k_1 is a correction factor to account for formulation that is sprayed, but not deposited, on the test surface. The target speed was not provided in the Study Report but was reported to be documented in the raw data.

Equipment Calibration Procedures: The Study Report states that a calibrated sprayboom was used in the study, but calibration procedures were not provided. It is not certain if the equipment used in this study was consistent with the proposed use for this product. A label was not provided with the study. Therefore, the label recommended application method is not known.

Was total deposition measured? Total deposition was measured using deposition coupons. The deposition coupons consisted of squares of alpha cellulose (3 in x 3 in). The coupons were backed with hexane-wiped heavy duty aluminum foil. The Study Report states that coupons were prepared according to Toxcon SOP No. M-015: *Preparation of Alpha Cellulose Deposition Coupon*. The coupons were present on the wooden platforms during test substance application.

D. Sampling:

Surface Areas Sampled: Vinyl and carpet flooring sections present on wooden platforms in SRR.

Replicates per sampling interval: Five subjects participated in the study. Hand presses were performed with both the left and right hand of the test subjects. Each subject performed one hand press with each hand on separate treated sections of vinyl or carpet flooring at 4, 12, 24, 72, 168, and 336 hours after application. Each hand press used a new section of treated vinyl or carpet flooring, resulting in a total of 10 hand press replicates for both vinyl and carpet per time interval. Triplicate samples of

percale for each flooring type were taken at 4, 8, 12, 24, 48, 72, 168, and 336 hours after application.

Number of sampling intervals: For hand press samples, 6 sampling intervals were conducted for roller samples, 8 sampling intervals were conducted.

Method and Equipment: Residue deposition was determined using alpha cellulose deposition coupons, transfer of residue to hands was determined using hand presses and dressing sponge wipes, and transfer of residue to percale was determined using percale indoor rollers.

Sampling Procedure(s) :

Deposition coupons - The deposition coupons were collected following a drying period after application of the test material. Disposable latex gloves were worn when the coupons were handled. The coupons were folded, so that the exposed side was on the inside, and then wrapped in hexane-wiped aluminum foil.

Hand residues - After application and collection of the deposition coupons, vinyl flooring and carpet sections were removed and moved to a hand press room. Each section of the carpet and vinyl flooring was placed in a hand press balance configuration at specific sampling intervals. The transfer of residues was determined based on the applied force (~8 kg) and contact duration (~20 s). The subjects washed and dried their hands prior to the hand presses. After the hand presses, the subjects' hands were cleaned with isopropyl alcohol wetted hand wipes (dressing sponges). Hand palmer surface areas were determined using an ink image of the palm side of each hand, which was then scanned into a computer to create a digital image of the hand. The computerized methods of calculating surface areas are described in Toxcon SOP No. M-010.

Indoor rollers - Percale was used as the test material for the indoor rollers. The Study Report stated that the design and use of the indoor rollers was described in Toxcon SOP M-011. The indoor roller assembly was fitted to the platforms to collect the roller samples. After each use of the roller, the frame assembly was wiped according to Toxcon SOP M-011.

3. Sample Handling and Storage:

The hand wipes from each hand were placed in separate pre-labeled 180 mL glass jars with Teflon-lined lids. Deposition coupons and percale samples were placed in aluminum containers and moved to freezer storage (<-5°C) within 3 hours of collection. All samples were stored in the dark at <-5°C until shipped for analysis. Samples were shipped to the analytical laboratory overnight in an insulated cooler with dry ice. The first shipment of study samples was received frozen at EN-CAS on November 13, 2001. A second shipment of study samples was received at ambient temperature on December 14, 2001. The study samples were immediately transferred to a laboratory freezer for storage where they remained frozen until they were thawed for analysis. Freezer storage temperatures at the laboratory were ≤10°C.

IV. ANALYTICAL METHODOLOGIES

A. Extraction method:

PER and PBO were extracted from percale and alpha cellulose coupons using 90:10 hexane:acetone and from dressing sponges using 70:30 hexane:acetone. The samples were shaken for approximately 30 minutes on a mechanical shaker.

B. Detection methods:

For PER, analysis was performed using a gas chromatograph equipped with an electron capture detector (GC/ECD). For the analysis of percale and alpha cellulose coupons a DB-1 column was used and for the analysis of dressing sponge samples a DB-5 column was used. A 1-ml aliquot of the final extract was transferred to an autoinjector vial containing 10 μ L of a 0.05% solution of dimethyldichlorosilane (DMDCS) in hexanes for analysis by GC/ECD. The DMDCS was added to compensate for matrix effects during instrumental analysis.

For PBO, analysis was performed using a high performance liquid chromatograph equipped with a fluorescence system (HPLC/FD). The extracts were taken to dryness, reconstituted in acetonitrile to an appropriate final volume, and injected into the HPLC/FD system. For a few samples, a step was modified where the aliquot was concentrated only to 0.5 mL and solvent exchanged into acetonitrile. The column switching consisted of a Zorbax phenyl pre-column programmed to transfer only the pre-column eluent in the PBO retention time region (approximately 1 minute window) to the Zorbax SB C18 analytical column. A 60:40 acetonitrile:water mixture was used in the pre-column, while an 80:20 acetonitrile:water mixture was used in the C18 analytical column. The fluorescence excitation and emission wavelengths monitored were 288 nm and 345 nm, respectively.

No further details regarding the GC/ECD or HPLC/FD conditions were provided. According to Analytical Phase Report provided in the Study Report, EN-CAS Analytical Method No. ENC-1/01, Rev 2, entitled *Analytical Method for the Determination of Permethrin and Piperonyl Butoxide (PBO) in/on Various Indoor Exposure Study Matrices* and EN-CAS Analytical Method No. ENC-2/01, Rev 1, entitled *Analytical Method for the Determination of Permethrin (PER) and Piperonyl Butoxide (PBO) in/on Isopropanol-Moistened Dressing Sponges* were used for the analyses performed in this study.

D. Method Validation:

Detailed method validation results were not provided in the Study Report. According to the Analytical Phase Report in the study, the results are reported in EN-CAS Project No. 01-0012, entitled *Permethrin and Piperonyl Butoxide (PBO) in/on Various Indoor Exposure Study Matrices* and in EN-CAS Project No. 01-0038, entitled *Permethrin and Piperonyl Butoxide (PBO) Validation Study: The Determination of PER and PBO in/on 2-Propanol (IPA) Moistened Dressing Sponges*. The LOQs provided in the Study Report are shown in Table 1.

Table 1. Validated LOQs

Matrix	LOQ (ug)	
	PER	PBO
Alpha Cellulose	10 ug (0.173 ug/cm ²)	8.66 ug (0.150 ug/cm ²)
Percales	0.100 ug (0.00080 ug/cm ²)	0.0866 ug (0.00069 ug/cm ²)
Dressing Sponge	0.200 ug	0.173 ug

Instrument performance and calibration:

Individual PER and PBO stock solutions were prepared from reference standard compounds by adding the reference material to volumetric flasks and bringing to volume with hexane. The resultant PER stock solutions were serially diluted with 90:10 hexane:acetone for the analysis of the alpha cellulose and cotton glove samples and with 70:30 hexane:acetone for the analysis of dressing sponges. For PBO, the stock solutions were diluted with acetonitrile. For PER, 5 concentrations were used to calibrate the system (0.005, 0.01, 0.02, 0.05, and 0.10 ug/mL). The GC/ECD and HPLC/FD responses were determined using the prepared calibration standards to perform a linear regression analysis.

E. Quality Control:

Lab Recovery: To obtain recovery and method performance data, concurrent laboratory control samples were fortified with the formulated product. At least two fortification levels were included with each analytical set. One fortification level was at approximately 1 to 2 times the LOQ and the other fortification level was at a level close to the highest expected level in the field samples. Results from the laboratory fortified samples are summarized in Table 3. Overall average recoveries \pm standard deviation for the alpha cellulose coupons were $100.7 \pm 2.6\%$ for PER and $94.0 \pm 5.1\%$ for PBO. Overall average recoveries \pm standard deviation for the percale coupons were $100 \pm 7.5\%$ for PER and $92.0 \pm 10.3\%$ for PBO. Overall average recoveries \pm standard deviation for the dressing sponges were $89.0 \pm 6.4\%$ for PER and $90.5 \pm 6.4\%$ for PBO.

Field Fortification: Samples of the alpha cellulose coupons, percale coupons, and dressing sponges were fortified at 7xLOQ and 40xLOQ, 15xLOQ and 500xLOQ, and 4xLOQ and 150xLOQ, respectively. Triplicate field fortification samples at each level were prepared on two separate days for each matrix using the non-volatile portion of the test substance. The solutions used to prepare the field fortifications were assayed at EN-CAS and the assay values were used to compute the quantity of PER and PBO actually applied to the field spikes. Actual values rather than nominal values of the field fortification solutions were used to calculate the fortification recoveries. The field fortification samples were stored and analyzed with the the samples. Field fortification results are summarized in Table 4. Overall average recoveries \pm standard deviation for the alpha cellulose coupons were $97.7 \pm 3.2\%$ for PER and $85.4 \pm 4.2\%$ for PBO. Overall average recoveries \pm standard deviation for the percale coupons were $96.9 \pm 3.6\%$ for PER and $90.5 \pm 17.8\%$ for PBO. Overall average recoveries \pm standard deviation for the dressing sponges were $102.8 \pm 8.9\%$ for PER and $97.8 \pm 3.1\%$ for PBO.

Control Samples: Field control samples were prepared according to Toxcon SOP M-016. Laboratory control samples were prepared by adding a volume of solvent approximately equal to the largest volume of solution used in the fortifications to samples for each flooring. The Study Report stated that none of the laboratory or field control samples showed any apparent residue of PER and PBO greater than or equal to the LOQ. However, according to the results in the Analytical Phase Report, PBO was detected in the percale field control samples at concentrations ranging from 0.909 ug to 4.25 ug.

Storage Stability: According to the Analytical Phase Report, the storage intervals used in this study (87 days for percale samples, 147 days for alpha cellulose samples, and 73 days for dressing sponge samples) are supported by stability data reported in EN-CAS Project 01-0013, entitled "*Freezer Storage Stability of Permethrin and Piperonyl Butoxide on Alpha-cellulose, Percale, Sponge/IPA, and Cotton Glove Matrices*". However, these results were not provided in this study. Additionally, the study did not specify the length of time the field fortification samples were stored prior to analysis.

Table 3. Summary of Concurrent Laboratory Fortification Recoveries

Approximate LOQ Fortification Level	No. of Samples	Average Fortification Level (ug)		Average Measured Residue (ug/sample)		Average Recovery (%)		Std. Dev.		Overall Average Recovery (%)		Std. Dev.		% RSD	
		PER	PBO	PER	PBO	PER	PBO	PER	PBO	PER	PBO	PER	PBO	PER	PBO
Alpha Cellulose															
LOQ	8	10.47	9.07	10.49	8.47	100.2	93.4	2.5	4.5	100.7	94.0	2.6	5.1	2.6	5.4
25xLOQ	6	262	226.9	262.3	209.5	100.1	92.3	2.4	4.7						
50xLOQ	2	524	453.8	540.2	453.7	103.1	100.0	NA	NA						
100xLOQ	1	1,048	907.6	1,095	884.2	104.5	97.4	NA	NA						
Percalé															
LOQ	5	0.105	0.0909	0.10	0.08	95.6	92.4	8.6	11.7	100.0	92.0	7.5	10.3	7.5	11.2
100xLOQ	1	10.50	9.09	10.76	6.48	102.5	71.3	NA	NA						
1000xLOQ	1	105	90.93	102.10	87.18	97.2	95.9	NA	NA						
2000xLOQ	1	210	181.9	223.4	170.0	106.4	93.5	NA	NA						
5000xLOQ	1	520	450.3	548.4	431.4	105.5	95.8	NA	NA						
6000xLOQ	1	628	543.8	682.2	538.1	108.6	99.0	NA	NA						
8000xLOQ	1	840	727.4	853.8	690.4	101.6	94.9	NA	NA						
Dressing Sponges															
LOQ	11	0.21	0.18	0.18	0.16	86.1	89.4	6.6	8.6	89.0	90.5	6.4	6.4	7.	7.1
5xLOQ	3	1.05	0.91	0.97	0.81	92.7	88.6	4.8	5.6						
10xLOQ	2	2.1	1.82	1.83	1.68	87.1	92.0	NA	NA						
25xLOQ	2	5.2-5.3	4.5-4.59	5.11	4.30	97.3	94.5	NA	NA						
50xLOQ	2	10.50	9.09	9.34	8.30	88.9	91.3	NA	NA						
100xLOQ	2	21	18.2	19.90	16.65	94.8	91.5	NA	NA						
500xLOQ	1	105	90.9	90.4	84.4	86.1	92.8	NA	NA						

Table 4. Summary of Field Fortification Recoveries.

Approximate LOQ Fortification Level	No. of Samples	Average Fortification Level (ug)		Average Measured Residue (ug/sample)		Average Recovery (%)		Std. Dev.		Overall Average Recovery (%)		Std. Dev.		% RSD	
		PER	PBO	PER	PBO	PER	PBO	PER	PBO	PER	PBO	PER	PBO	PER	PBO
Alpha Cellulose															
7xLOQ	6	67.9	61.9	67.9	54.7	100.0	88.4	2.8	2.5	97.7	85.4	3.2	4.2	3.2	5.0
40xLOQ	6	407.1	371.1	388.5	306.0	95.4	82.5	1.2	3.5						
Percale															
15xLOQ	6	15.3	13.7	14.7	13.3	96.3	97.1	2.5	24.1	96.9	90.5	3.6	17.8	3.8	19.7
500xLOQ	6	542.8	494.8	529.1	415.7	97.5	84.0	4.7	4.0						
Dressing Sponge															
4xLOQ	6	0.77	0.68	0.85	0.68	110.5	99.5	4.8	3.1	102.8	97.8	8.9	3.1	8.6	3.2
150xLOQ	6	30.6	27.3	29.1	26.3	95.2	96.1	2.8	2.1						

V. RESULTS

A. Alpha Cellulose and Deposition of Formulation:

Residues were reported for both PER and PBO. Versar corrected the PBO residue data for field fortification recoveries because recoveries were less than 90% for PBO. The Registrant did correct for field fortification recoveries. The average deposition of PER and PBO reported by the study author for each sprayboom run is provided in Table 5. The reported average deposition ranged from 4.68 to 5.75 ug/cm² for PER and from 3.94 to 4.81 ug/cm² for PBO. Versar corrected the PBO deposition coupon residue data for the average fortification recovery of 85.4%. As shown in Table 5, the corrected deposition values for PBO ranged 4.58 to 5.62 ug/cm². For PER, the actual deposition ranged from 118 to 145% of the target deposition and for PBO, the actual deposition (corrected for field fortification recovery) ranged from 116 to 142% of the target deposition. The average deposition value for each type of run was used in the percent transferability (percent of application) calculations for the 2 sprayboom runs on carpet and the 2 sprayboom runs on vinyl. For the collection of percale samples, the average of the two runs was used in the calculations.

B. Hand Residues:

Residues transferred to bare hands from carpet and vinyl were calculated by the study author and Versar for each hand of the test subjects at 4, 12, 24, 72, 168, and 336 hours after application. The study author used a value of zero in the calculations when residues were reported to be below the LOQ. Versar used ½ the LOQ when residues were reported to be below the LOQ. The residues transferred from bare hands to the flooring were not corrected for field fortification by the study author or by Versar because recoveries were >90%. Versar's calculated transfer residues are provided in Table 6. According to both the study author's and Versar's calculations, average PER and PBO residues transferred from vinyl to the hand were highest after 4 hours and lowest after 336 hours. The study author calculated average values ranging from 0.91 to 271.42 ng/cm² for PER and from 0.0 to 160.26 ng/cm² for PBO. Versar calculated average values ranging from 2.01 to 271.42 ng/cm² for PER and from 1.19 to 160.26 ng/cm² for PBO. As all PER and PBO residues transferred to bare hands from carpet were above the LOQ, the study author's and Versar's calculations for this portion of the study were in agreement. The average residues transferred from carpet to the hand were highest after 4 hours for PER and PBO (192.96 and 168.76 ng/cm², respectively) and lowest after 168 hours for PER (128.68 ng/cm²) and after 336 hours for PBO (90.57 ng/cm²).

The percent of residue transferred to the hands after contact with either treated vinyl or carpet surfaces was calculated as the ratio of the amount of residue present on the hand divided by the average residue found on the alpha cellulose coupons for that particular sprayboom run. The study author used uncorrected residue found on the coupons to calculate the percent transfer. Because the average field fortification recovery for PBO on alpha cellulose coupons was <90%, Versar corrected the PBO residue on the alpha cellulose coupons for field fortification recovery. Versar did not correct the PER residue on the alpha cellulose coupons for field fortification results because recovery was >90% for PER. The percent of residue transferred from vinyl to the hands after application was reported by the study author to range from 5.14% for PER and 3.57% for PBO at 4 hours after application to 0.02% for PER and 0.0% for PBO at 336 hours after application. The percent of residue transferred from carpet to the hands after application was reported by the study author to range from 3.79% for PER and 4.20% for PBO at 4 hours after application to 2.53% for PER and 2.25% for PBO at 168 and 336 hours after application, respectively. The percent of residue transferred from vinyl to the hands was calculated by Versar and ranged from 5.14% for PER and 3.05% for PBO at 4 hours after application to 0.04% for PER and 0.02% for PBO at 336 hours after application. The percent of residue transferred from carpet to the hands was calculated by Versar and ranged from 3.79% for PER and 3.59% for PBO at 4 hours after application to 2.53% for PER and 1.93% for PBO at 168 and 336 hours after application, respectively.

C. Percale Roller Residues:

Residues transferred to percale from carpet and vinyl were calculated by the study author and Versar at 4, 8, 12, 24, 48, 72, 168, and 336 hours after application. The study author used a value of zero in the calculations when residues were reported to be below the LOQ. Versar used ½ the LOQ when residues were reported to be below the LOQ. The residues transferred from percale to the flooring were not corrected for field fortification by the study author or by Versar because recoveries were >90%. Versar's calculated transfer residues are provided in Table 7. According

to both the study author's and Versar's calculations, the average residues transferred from vinyl to the percale were highest after 4 hours for PER and PBO (114 and 63 ng/cm²) and lowest after 336 hours for PER (1 ng/cm²) and after 168 hours for PBO (1 ng/cm²). For the transfer from carpet to the percale, average residues were highest after 24 hours for PER (267 ng/cm²) and PBO (205 ng/cm²) and lowest after 12 hours for PER (206 ng/cm²) and after 336 hours for PBO (132 ng/cm²).

The percent of residue transferred to the percale after contact with either treated vinyl or carpet surfaces was calculated as the ratio of the amount of residue present on the hand divided by the average residue found on the alpha cellulose coupons for the two sprayboom runs conducted on vinyl and the two sprayboom runs conducted on carpet. The study author used uncorrected residue found on the coupons to calculate the percent transfer. Because the average field fortification recovery for PBO on alpha cellulose coupons was <90%, Versar corrected the PBO residue on the alpha cellulose coupons for field fortification recovery. Versar did not correct the PER residue on the alpha cellulose coupons for field fortification results because recovery was >90% for PER. The percent of residue transferred from vinyl to the percale after application was reported by the study author to range from 2.08% for PER and 1.38% for PBO at 4 hours after application to 0.02% for PER at 336 hours after application and 0.02% for PBO at 168 hours after application. The percent of residue transferred from carpet to the hands after application was reported by the study author to range from 5.69% for PER and 5.15% for PBO at 24 hours after application to 4.39% for PER at 12 hours after application and 4.12% for PBO at 168 hours after application. The percent of residue transferred from vinyl to the percale was calculated by Versar and ranged from 2.08% for PER and 1.17% for PBO at 4 hours after application to 0.02% for PER at 336 hours after application and 0.02% for PBO at 168 hours after application. The percent of residue transferred from carpet to the percale was calculated by Versar and ranged from 5.7% for PER and 4.4% for PBO at 24 hours after application to 4.4% for PER and 2.8% for PBO at 12 and 336 hours after application, respectively.

VI. CONCLUSION

Residues remaining on hands and percale following contact with either a treated vinyl or carpet flooring surface were determined from 4 hours after application to 336 hours after application. The percent of residue transferred from vinyl to the hands after application was reported by the study author to range from 5.14% for PER and 3.57% for PBO at 4 hours after application to 0.02% for PER and 0.0% for PBO at 336 hours after application. The percent of residue transferred from carpet to the hands after application was reported by the study author to range from 3.79% for PER and 4.20% for PBO at 4 hours after application to 2.53% for PER and 2.25% for PBO at 168 and 336 hours after application, respectively. The percent of residue transferred from vinyl to the percale after application was reported by the study author to range from 2.08% for PER and 1.38% for PBO at 4 hours after application to 0.02% for PER at 336 hours after application and 0.02% for PBO at 168 hours after application. The percent of residue transferred from carpet to the hands after application was reported by the study author to range from 5.69% for PER and 5.15% for PBO at 24 hours after application to 4.39% for PER at 12 hours after application and 4.12% for PBO at 168 hours after application.

Versar also calculated the percent of residue transferred from vinyl flooring and carpet to bare hands and percale. The percent of residue transferred from vinyl to the hands was calculated by Versar and ranged from 5.14% for PER and 3.05% for PBO at 4 hours after application to 0.04% for PER and 0.02% for PBO at 336 hours after application. The percent of residue transferred from carpet to the hands was calculated by Versar and ranged from 3.79% for PER and 3.59% for PBO at 4 hours after application to 2.53% for PER and 1.93% for PBO at 168 and 336 hours after application, respectively. The percent of residue transferred from vinyl to the percale was calculated by Versar and ranged from 2.08% for PER and 1.17% for PBO at 4 hours after application to 0.02% for PER at 336 hours after application and 0.02% for PBO at 168 hours after application. The percent of residue transferred from carpet to the percale was calculated by Versar and ranged from 5.7% for PER and 4.4% for PBO at 24 hours after application to 4.4% for PER and 2.8% for PBO at 12 and 336 hours after application, respectively.

In general, the PER and PBO residues transferred from treated vinyl to either percale or bare hands decreased rapidly over time and PER and PBO residues transferred from treated carpet to either percale or bare hands decreased slowly over time. For vinyl, the percent of PER transferred to percale or bare hands is higher than the percent of PBO transferred. For carpet, the percent of PER transferred to percale or bare hands is similar to the percent of PBO transferred to percale or bare hands. Additionally, for vinyl, the percent of PER and PBO

transferred to bare hand was higher than transferred to percale. For carpet, the percent of PER and PBO transferred to percale was higher than transferred to bare hand.

LIMITATIONS OF THE STUDY:

The protocol provided with the study along with OPPTS Series 875 Part B, Guideline 875.2300: Indoor Surface Residue Dissipation, Postapplication and Part C Guidelines were used to review the study. Overall, the majority of the procedures performed and the quality of the data generated in this study conformed to the criteria set forth in the protocol and guidelines. However, certain issues of concern were noted:

- A specific application rate was not provided in the Study Report. Application was based on a target deposition rate determined in another Study Report.
- Calibration procedures for the application equipment were not provided in the Study Report. It is not certain if the equipment used in this study was consistent with the proposed use for this product. A label was not provided with the study. The label recommended application method is not known
- The study author did not correct the PBO coupon deposition residue data for field fortification recoveries, which were below 90%.
- The method validation recoveries were not provided in the study.

Table 5. Deposition of PER and PBO – Results of Alpha Cellulose Coupons

Sample	Run Number	Study Author's Reported Deposition ($\mu\text{g}/\text{cm}^2$) ^a		Average Corrected Deposition \pm Standard Deviation ($\mu\text{g}/\text{cm}^2$) ^{a, b}		Percent of Target Deposition ^c	
		PER	PBO	PER	PBO	PER	PBO
Bare Hand (Dressing Sponge) Runs							
Vinyl	1	5.28 \pm 1.14	4.49 \pm 0.96	5.28 \pm 1.14	5.25 \pm 1.13	133 \pm 29	133 \pm 28
Carpet	1	5.09 \pm 0.72	4.02 \pm 0.72	5.09 \pm 0.72	4.70 \pm 0.84	129 \pm 18	119 \pm 21
Roller (Percale) Runs							
Vinyl	1	5.21 \pm 1.00	4.35 \pm 0.83	5.21 \pm 1.00	5.09 \pm 0.97	132 \pm 25	129 \pm 24
	2	5.75 \pm 0.85	4.81 \pm 0.70	5.75 \pm 0.85	5.62 \pm 0.82	145 \pm 21	142 \pm 21
	Average of Runs 1 and 2 ^d	5.48 \pm 0.38	4.58 \pm 0.33	5.48 \pm 0.95	5.36 \pm 0.92	138 \pm 24	135 \pm 23
Carpet	1	4.69 \pm 0.96	4.02 \pm 0.79	4.68 \pm 0.96	4.70 \pm 0.92	118 \pm 24	119 \pm 23
	2	4.68 \pm 1.08	3.94 \pm 0.90	4.68 \pm 1.08	4.58 \pm 1.05	118 \pm 27	116 \pm 27
	Average of Runs 1 and 2 ^d	4.69 \pm 0.01	3.98 \pm 0.06	4.68 \pm 1.00	4.64 \pm 0.97	118 \pm 25	117 \pm 25

a Deposition ($\mu\text{g}/\text{cm}^2$) = PER and PBO residues found on alpha cellulose coupons ($\mu\text{g}/\text{sample}$)/surface area of coupon (57.8 cm^2).

b PBO deposition corrected for an overall average field fortification recovery of 85.4%. The PER deposition was not corrected because the overall average field fortification recovery was 97.7% for PER.

c Calculated by dividing the corrected average deposition by the target deposition (3.96 g/cm^2) and multiplying by 100.

d The average deposition from both sprayboom runs was used to calculate the percent of application transferred from the carpet or vinyl to the percale for all samples.

Table 6. Summary of PER and PBO Hand Residues from Contact with Treated Carpet and Vinyl Flooring

Time Interval (hours)	Average Residue (ug/sample) ^a		Average Residue (ng/cm ²) ^b		Standard Deviation (ng/cm ²)		Deposition Coupon (ug/cm ²) ^c		% of Application ^d		Standard Deviation (%)	
	PER	PBO	PER	PBO	PER	PBO	PER	PBO	PER	PBO	PER	PBO
Carpet												
4	15.37	13.43	192.96	168.76	109.2	93.8	5.09	4.70	3.79	3.59	2.15	2.00
12	12.01	10.00	158.97	132.60	73.2	62.2			3.12	2.82	1.44	1.32
24	11.59	9.45	150.03	122.68	40.0	32.3			2.95	2.61	0.79	0.69
72	13.46	10.77	173.69	138.93	56.5	44.9			3.41	2.96	1.11	0.96
168	9.80	7.48	128.68	99.58	33.8	26.3			2.53	2.12	0.66	0.56
336	10.31	6.93	134.52	90.57	41.1	32.0			2.64	1.93	0.81	0.68
Vinyl												
4	19.43	11.46	271.42	160.26	147.11	97.44	5.28	5.25	5.14	3.05	2.79	1.85
12	4.45	2.57	61.18	35.25	41.98	26.72			1.16	0.67	0.80	0.51
24	2.04	1.13	28.75	15.84	12.45	6.42			0.54	0.30	0.24	0.12
72	0.79	0.29	10.84	4.10	4.88	1.25			0.21	0.08	0.09	0.02
168 ^e	0.30	0.13	4.26	1.76	1.64	0.97			0.08	0.03	0.03	0.02
336 ^e	0.15	0.09	2.01	1.19	1.53	0.13			0.04	0.02	0.03	0.00

a Average of 10 replicates (5 subjects using both hands) for all carpet and vinyl hand press time intervals.

b Average residue (ng/cm²) calculated by taking individual replicate residues (μg/samples) and dividing by individual replicate hand surface areas provided in the Study Report.

c Calculated as the ratio of the amount of residue present on the hand divided by the average residue found on the alpha cellulose coupons for that particular sprayboom run.

d The PBO deposition residue was corrected for an average field recovery of 85.4%.

e Included samples with residues reported to be below the LOQ; used 1/2 the LOQ in calculations (LOQ of 0.20 μg/sample).

Table 7. Summary of PER and PBO Percal Residues from Contact with Treated Carpet and Vinyl Flooring

Time Interval (hours)	Average Residue (ug/sample) ^a		Surface Area (cm ²)	Average Residue (ng/cm ²) ^b		Standard Deviation (ng/cm ²)		Deposition Coupon (ug/cm ²) ^c		% of Application ^d		Standard Deviation (%)	
	PER	PBO		PER	PBO	PER	PBO	PER	PBO	PER	PBO	PER	PBO
Carpet													
4	649	558	2,787	233	200	25.6	24.5	4.68	4.64	5.0	4.3	0.55	0.53
8	580	472		208	169	38.4	28.7			4.4	3.7	0.82	0.62
12	575	463		206	166	14.3	20.1			4.4	3.6	0.31	0.43
24	744	571		267	205	69.9	39.8			5.7	4.4	1.49	0.86
48	635	500		228	179	43.3	33.5			4.9	3.9	0.92	0.72
72	636	488		228	175	28.4	19.4			4.9	3.8	0.61	0.42
168	664	457		238	164	17.9	15.3			5.1	3.5	0.38	0.33
336	608	368		218	132	43.1	26.0			4.7	2.8	0.92	0.56
Vinyl													
4	317.03	174.47	2,787	114	62.60	39.8	25.4	5.48	5.36	2.08	1.17	0.73	0.47
8	64.19	30.28		23.03	10.87	3.47	1.62			0.42	0.20	0.06	0.03
12	44.87	20.30		16.10	7.28	9.44	5.20			0.29	0.14	0.17	0.10
24	35.05	15.97		12.58	5.73	2.96	1.31			0.23	0.11	0.05	0.02
48	13.95	6.29		5.01	2.26	1.68	0.65			0.09	0.04	0.03	0.01
72	16.39	6.69		5.88	2.40	1.92	0.68			0.11	0.04	0.04	0.01
168	6.61	3.05		2.37	1.09	1.31	0.64			0.04	0.02	0.02	0.01
336	2.93	8.31		1.05	2.98	0.32	0.19			0.02	0.06	0.01	0.00

a Average of 10 replicates (5 subjects using both hands) for all carpet and vinyl hand press time intervals.

b Average residue (ng/cm²) calculated by taking individual replicate residues (μg/samples) and dividing by surface area of percale coupons (2787 cm²).

c The PBO deposition residue was corrected for an average field recovery of 85.4%.

d Calculated as the ratio of the amount of residue present on the percale divided by the average residue found on the alpha cellulose coupons for both carpet sprayboom runs or both vinyl sprayboom runs.

APPENDIX A

Compliance Checklist for “*Measurement of Transfer of Pyrethrin and Piperonyl Butoxide Residues from Vinyl and Carpet Flooring Treated with a Fogger Formulation as a Function of Time*”

Compliance Checklist for "Measurement of Transfer of Permethrin and Piperonyl Butoxide Residues from Vinyl and Carpet Flooring Treated with a Fogger Formulation as a Function of Time"

**GUIDELINE 875.2300
INDOOR SURFACE RESIDUE DISSIPATION
POSTAPPLICATION**

1. *The test substance must be the typical end use product of the active ingredient.* It is unclear if this criterion was met. The test product was an unidentified product and no label was provided.
2. *The production of metabolites, breakdown products, or the presence of contaminants of potential toxicologic concern, should be considered on a case-by-case basis.* This criterion does not apply to this study. There was no mention of metabolites, breakdown products, or other contaminants.
3. *Indoor surface residue studies should be conducted under ambient conditions similar to those encountered during the intended use season, and should represent reasonable worst case conditions.* This criterion was met.
4. *Ambient conditions (i.e., temperature, barometric pressure, ventilation) should be monitored.* This criterion was mostly met. Target conditions were identified and apparently met, but, monitoring data were not provided.
5. *The end use product should be applied by the application method recommended on the label. Information that verifies that the application equipment (e.g., sprayer) was properly calibrated should be included.* These criteria were not met. It is unclear if the end-use product was applied by the recommended application method since no label was provided. Information on calibration of the application equipment was not provided.
6. *The application rate used in the study should be provided and should be the maximum rate specified on the label. However, monitoring following application at a typical application rate is more appropriate in certain cases.* This criterion was not met. Application was based on a target deposition rate determined in another study.
7. *If multiple applications are made, the minimum allowable interval between applications should be used.* This criterion does not apply to this study; multiple applications were made, but to different surfaces each time.
8. *Indoor surface residue (ISR) data should be collected from several different types of media (e.g., carpeting, hard surface flooring, counter tops, or other relevant materials).* This criterion does not apply to this study. The objective was to determine hand and roller (percale) residue from contact with a treated vinyl flooring and carpet sections.
9. *Sampling should be sufficient to characterize the dissipation mechanisms of the compound (e.g., three half-lives or 72 hours after application, unless the compound has been found to fully dissipate in less time; for more persistent pesticides, longer sampling periods may be necessary). Sampling intervals may be relatively short in the beginning and lengthen as the study progresses. Background samples should be collected before application of the test substance occurs.* This criterion was mostly met. Sampling was continued up to 336 hours after application, however, dissipation mechanisms were not characterized since this was not the objective of the study.
10. *TriPLICATE, randomly collected samples should be collected at each sampling interval for each surface type.* This criterion was met. For hand residues, samples were taken of dressing sponges following hand rinses of both hands of five test subjects. Ten wipe samples were taken after the hand presses for a total of 10 replicates. Triplicate roller (percale) samples were taken from each flooring type at each sampling interval.
11. *Samples should be collected using a suitable methodology (e.g., California Cloth Roller, Polyurethane Roller, Drag Sled, Coupons, Wipe Samples, Hand Press, vacuum cleaners for dust and debris, etc.) for indoor surfaces.* This criterion was met.

12. *Surface sampling should be conducted in conjunction with air sampling. Enough duplicate air samples should be taken in a room to establish a dissipation curve.* This criterion was not met.

13. *Samples should be stored in a manner that will minimize deterioration and loss of analytes between collection and analysis. Information on storage stability should be provided.* This criterion was most likely met. According to the Analytical Phase Report, the storage intervals used in this study (87 days for percale samples, 147 days for alpha cellulose samples, and 73 days for dressing sponge samples) are supported by stability data reported in EN-CAS Project 01-0013, entitled “Freezer Storage Stability of Permethrin and Piperonyl Butoxide on Alpha-cellulose, Percale, Sponge/IPA, and Cotton Glove Matrices”. However, these results were not provided in the study.

14. *Validated analytical methods of sufficient sensitivity are needed. Information on method efficiency (residue recovery), and limit of quantitation (LOQ) should be provided.* This criterion was partially met. LOQs were provided, however, the recoveries of the method validation study are in another report.

15. *Information on recovery samples must be included in the study report. A complete set of field recoveries should consist of at least one blank control sample and three or more each of a low-level and high-level fortification. These fortifications should be in the range of anticipated residue levels in the field study.* This criterion was mostly met. Two sets of duplicate blank control samples and two sets of triplicate field fortification samples at a high and low level were included in the study. PBO residues were detected above the LOQ in the percale field fortification blank samples.

16. *Raw residue data must be corrected if appropriate recovery values are less than 90 percent.* This criterion was not met. The average recovery value for the alpha cellulose coupons was reported to be below 90%, however, the raw data were not corrected by the study author.

17. *Indoor surface residues should be reported as mg per m² or cm² of surface sampled. Distributional data should be reported, to the extent possible.* This criterion was partially met. Hand residue data were reported in ng per cm² of surface sampled.

18. *Reported residue dissipation data in conjunction with toxicity data should be sufficient to support the determination of a reentry interval.* This criterion does not appl